Official Title: Does an occupational therapy program enhance mental health outcomes for veterans who scuba dive

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Study Protocol and Statistical Analysis Plan

METHODS

Study Design

For this study, we will be using a quasi-experimental design to compare the effectiveness of two groups: occupational therapy in combination with SCUBA diving in comparison to SCUBA diving alone. Data will be collected through semi-structured interviews and standardized assessments to assess the impact on psychosocial skills and occupational engagement.

Inclusion/Exclusion Criteria

SCUBA diver veterans who have participated in the WAVES Project for at least 3 months and have completed 3 open water dives. Participants must be proficient in written and verbal English. Veterans must be between 18-95 years of age.

Recruitment

Recruitment Method Info

We will recruit up to 15 participants in the control and experimental group for a total of 30 veterans from the WAVES Project facility. Purposeful and snowballing sampling methods will be applied to recruit participants via flyer. The flyer will be sent via email to the director of the WAVES project. The director will then forward the electronic flyer to their members via email or Facebook. Additionally, a meeting will be scheduled at the WAVES Project facility where the researchers will reach out to the veterans via a verbal recruitment script (see Appendix B) and a physical flyer (Appendix A). Those who are interested in participating will contact the researchers via email or phone and will be scheduled to

attend the first group meeting. At the group meeting the research project will be overviewed and the informed consent form will be provided.

Instruments & Data Collection

This study will include the following instruments: Intake Focus Group (Appendix D), Demographic Questionnaire (Appendix E), COPM (Appendix F), PCL-5 (Appendix G), DASS-21 (Appendix H), Discharge Focus Group (Appendix I) and Follow-Up Phone Script (Appendix J).

A Intake Focus Group consists of four sections and will be used to identify participants' experiences with SCUBA diving, impact of negative emotions on daily life and coping strategies. Focus groups will be held with those in the experimental group and control group separately..

The demographic questionnaire will obtain information about participants' age, gender, ethnicity, marital status, study and work commitments.

The Canadian Occupational Performance Measure (COPM) is "an individualized outcome measure designed to assess clients' perception of their occupational performance and satisfaction with that performance" (Donnelly, O'Neill, Bauer, & Letts, 2017). A systematic review (Parker & Sykes, 2006) found that this assessment allows clients to identify personal goals they would like to work on throughout their time in occupational therapy (Donnelly, O'Neill, Bauer, & Letts, 2017). It has also been used in research studies to measure change in perceived performance and satisfaction with performance (Plach, Sells, 2013).

The PTSD Checklist for DSM-5 (PCL-5) assesses the 20 DSM-5 symptoms of PTSD through a 20-item self-report measure. There are several purposes of the PCL-5, including: "monitoring symptom change during and after treatment, screening individuals for PTSD, and making a provisional PTSD diagnosis." In the PCL-5, individuals are presented with a list of problems people may have as a result of

a stressful situation. Individuals are asked to indicate how much they have been bothered by this problem in the past month. Problems can be rated as “not at all, a little bit, moderately, quite a bit, or extremely” (Weathers et al., 2013). The PCL-5 demonstrates sound psychometric properties according to Wortmann et al. (2016).

The Depression Anxiety and Stress Scales (DASS) is a screening tool to assess symptoms of depression, anxiety, and stress in community settings (Tran, Tran, & Fisher, 2013). The DASS-21 asks 21 questions and is comprised of three subscales: The Depression sub-scale which measures hopelessness, low self-esteem, and low positive affect; the Anxiety scale which assesses autonomic arousal, musculoskeletal symptoms, situational anxiety and subjective experience of anxious arousal; and the Stress scale which assesses tension, agitation, and negative affect (Tran, Tran, & Fisher, 2013). The DASS-21 will also be used as a quantitative outcome measure pre and post-test to measure changes in mental health.

Discharge focus groups will be used to identify coping strategies after participating in occupational therapy intervention in combination with SCUBA or SCUBA diving alone. Therefore, individual focus groups will be held for the experimental and control groups. Qualitative information will provide in depth information about participants’ experiences with SCUBA diving and occupational therapy, and the impact on mental health and daily life.

Follow-up phone interviews will be held individually with each participant in the experimental group. The interview will consist of six questions and be used as a qualitative outcome measure to explore the effects of occupational therapy in combination with SCUBA diving and its impact on participants’ mental health and daily life.

Informed Consent Process

Veterans interested in the study will be scheduled to attend a group meeting. At the meeting, the research study will be briefly described and the informed consent document will be provided and reviewed. Those who are interested in participating will sign the consent form prior to completing pre-assessments. .Those who are interested in participating will sign the consent form prior to completing pre-assessments.

Procedures

After receiving IRB approval, we will:

1. Email the flyer (see Appendix A) to the WAVES director and ask the director to send the flyer to members of the WAVES.
2. Schedule recruitment opportunities to present the flyer (see Appendix A) and verbal recruitment script (see Appendix B) at end of a *WAVES* session to recruit up to 30 *WAVES* veterans with mental health conditions. Provide signup sheet to sign up if interested.
3. Hand out flyers (with contact information i.e. phone number and email) to participants of *WAVES.*
4. Individuals interested may contact the research team via email and phone to sign up for the study.
5. Interested individuals will arrive at the group meeting at the scheduled time (the group meeting will last 1 ½ hours).
6. At the group meeting, provide a brief overview of the study and informed consent document, approximately 5 minutes.
7. Obtain written informed consent to participate in study, approximately 10 minutes.
8. Randomly assign participants into one of two groups before pre-testing: Experimental group or control group, approximately 10 minutes.

9. Provide further explanation about SCUBA, occupational therapy and the research program, approximately 10 minutes.
10. For pre-test questionnaires, have participants complete the COPM (Appendix F), PCL-5 (Appendix G), and DASS-21 (Appendix H). approximately 25 minutes.
11. The group will then split and focus groups (see Appendix K) will be held for the experimental and control groups, approximately 25 minutes.
12. Conclude the meeting and review the upcoming schedule (as described in the following), approximately 5 minutes.
13. Participants in the **experimental group** will complete 3-week OT program for 1.5 hours each week. After 4 weeks total, a follow-up phone call will be given with general questions regarding experience with OT and SCUBA diving.

(See Appendix K for more details of research program)

Week 1	**Week 2**	**Week 3**	**Week 4**	**Week 8**
Informed consent Pre-test assessments Focus Group (audio will be recorded and transcribed)	**<u>OT Program</u>** Orientation Mindfulness strategies Journaling activity	**<u>OT Program</u>** Social community reflection Focus group to reflect on week 1 (audio will be recorded and transcribed) (See focus group questions in Appendix K)	**<u>OT Program</u>** Social community reflection Focus group to reflect on week 2 (audio will be recorded and transcribed) (See focus group questions in Appendix K) Discharge focus	Follow-up phone call after 4 weeks (audio recorded and transcribed)

Total time: 1.5 hours	**Total time: 1.5 hours**	Journaling activity Trust-building activity **Total time: 1.5 hours**	group (audio will be recorded and transcribed) Journaling activity Post-test assessments **Total time: 1.5 hours**	**Total time: 1.5 hours**

14. Participants in **control group** will continue SCUBA diving without OT. They will participate in a discharge focus group discussion and complete post-test assessments. However, they will not receive a follow up phone call.

Week 1	**Week 2**	**Week 3**	**Week 4**
Informed consent Pre-test assessments	SCUBA dive without OT	SCUBA dive without OT	SCUBA dive without OT Post-test assessments

Focus Group (audio will be recorded and transcribed) **Total time: 1.5 hours**			Discharge focus group (audio will be recorded and transcribed) **Total time: 1.5 hours**

15. For post-test, have participants complete the COPM (Appendix F), PCL-5 (Appendix G), and DASS-21 (Appendix H).
16. The discharge focus group will completed for both the experimental and control groups during week 4.
17. Complete field notes.
18. Transcribe focus groups within two weeks.
19. Complete follow up phone call after 4 weeks, for experimental group only, following the follow-up phone script (Appendix J).
20. Upload interviews to DeDoose for qualitative data analysis
21. Utilize SPSS to analyze quantitative data from COPM, PCL-5, and DASS-21

Risk and Injury

Breach of Confidentiality

- Pseudonyms will be used to identify participants; a master list will document each participant's pseudonym. The master list will be stored separately to all data collected. All interviews will be transcribed by using headphones to ensure others will not hear the data. Data collected from focus groups, interviews and questionnaires will be stored electronically and in hard copy. Data

in hard copy will be kept in a locked file and electronic data will be password protected. Within two weeks of recording and following audit for correctness of transcriptions, the audio recordings will be destroyed.

Discomfort/vulnerability disclosing personal information

Some focus group or interview questions may be upsetting or uncomfortable for participants. Participants will be informed that they do not need to share any information that they wish not to with the group or that makes them uncomfortable. If the participants experience emotional discomfort at any time throughout the duration of the study, they may refuse to answer the question or withdraw from the study at any time.

Data Management Including Labeling & Storage Data

Subject/Data Confidentiality

- To protect the participants' identity, the researchers will assign pseudonyms and create a master list. The master list containing participant's legal names will be available only to the researchers. Electronic data will be stored in secure files on a password protected school shared server. The master list will be stored separately to collected data.
- All hard copy data will be stored in a locked file until the study is completed, in a secure office at Loma Linda University.
- Upon completion of the data collection, the data will be stored for a minimum of three years in a locked file in the school of Allied Health Professions at Loma Linda University. Three years post research data will be destroyed.

Data Analysis

- Qualitative data will include focus groups and interviews and these will transcribed verbatim. Transcripts will be coded individual, and then together as a group. A codebook will be created and then categorized to organize emerging themes.
- Once the quantitative data is completed, it will be uploaded into a database in SPSS for analysis. Demographic information will be analyzed using descriptive analysis. Changes in COPM, PCL-5, and DASS-21 scores will be tested using paired samples t-tests. Further, differences between groups will be analyzed using independent samples t-tests.